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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,647	01/20/2004	Benedikt Sas	4532680/22350 (KEM 78)	1021

26386 7590 11/21/2005

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DES MOINES, IA 50309-3993

EXAMINER

JOHNSEN, JASON H

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 11/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/760,647

Applicant(s)

SAS ET AL.

Examiner

Jason H. Johnsen

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 8-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-4 and 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on N/A is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The amendment filed on August 24, 2005 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

- (A) Comments regarding office action have been provided drawn to:
- (iii) 102(b) rejection of claims 1 and 2 by Schramm et al., which has been withdrawn in view of applicant's amendments;
 - (iii) 102(b) rejection of claims 1 and 2 by Matulic-Adamic et al., which has been withdrawn in view of applicant's amendments;
 - (iii) 102(b) rejection of claims 1 and 5-7 by Takatsuki et al., which has been withdrawn in view of applicant's amendments;
 - (iv) 112, 1st paragraph rejection of claims 5-7, which has been withdrawn in view of applicant's amendments;
 - (v) 112, 2nd paragraph rejection of claims 1-4, which has been withdrawn in view of applicant's amendments;
 - (vi) 112, 1st paragraph rejection of amended claims 1-4, and 8-10 is newly cited.
 - (vii) 112, 1st paragraph rejection of claim 1 is newly cited.
 - (viii) 112, 2nd paragraph rejection of claim 1 is newly cited and necessitated by amendment.

2. Claims 1-4, and 8-10 are pending in the case.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-4 and 8-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains,

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or with which it is most nearly connected, to make and/or use the invention. The following reason(s) apply:

The nature of the invention in the instant application has claims which embrace a diversity of chemically and physically distinct compounds, wherein R_1 and R_2 form a ring, and wherein R_3 and R_4 form a ring, and where all of these diverse compounds treat an infection caused by herpesviridae or poxiridae. While compounds where R_1 and R_2 or R_3 and R_4 form dioxolane and dioxolane derivatives, there is insufficient guidance for preparing additional “rings” which would be effective in treating herpesviridae or oxiridae caused infections. Only compounds wherein R_1 and R_2 or R_3 and R_4 are a dioxolane or dioxolane derivative have been made.

Furthermore, besides the language of R_1 and R_2 and/or R_3 and R_4 forming a ring being so broad as to encompass innumerable ring structures, none of these compounds, other than the few mentioned above, have not been tested using the in vitro assays described in the specification. There is no data to support a conclusion of their effectiveness in treating herpesviridae or poxiridae caused infections, or any other type of infection for that matter. Examples should be of sufficient scope as to justify the scope of the claim. However, the generic claims are much broader in scope than is represented by the testing. The definitions of the R_1 , R_2 , R_3 and R_4 substituents forming rings embrace many structurally divergent groups not represented at all in testing, since testing for the instant compounds is not seen in the specification. Markush claims must be provided with support in the disclosure when the “working examples” fail to include written description(s) which teach how to make and use Markush members embraced thereby in full, clear and exact terms. See *In re Fouch*, 169 USPQ 429.

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This area of activity can be expected to be highly structure specific and unpredictable, as is generally true for chemically based pharmacological activity. In view of the structural divergence in the claims, one skilled in the art could not reasonably extrapolate the activities of some of the claimed compounds to the other structurally divergent compounds which are being used for their physiological activity, the scope of the claims must have a reasonable correlation to the scope of enablement provided by the specification. *See In re Surrey 151 USPQ 724* regarding sufficiency of disclosure for a Markush group. No reasonable assurance has been made that the instant compounds as an entire class have the required activities needed to practice the invention, e.g. "treat an infection caused by herpesviridae or poxiridae." Thus, factors such as "sufficient working examples," "the level of skill in the art," and "predictability in the art" have been demonstrated to be sufficiently lacking in the instant case for the scope being claimed.

2. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administering an effective amount of one compound of the formula of claim 1, does not reasonably provide enablement for administering an effective amount of multiple compounds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. There is support in the specification for administering a single active agent, but not multiple agents. There is no teaching as to what ratio the skilled artisan is to combine multiple compounds or what two or more active agents are to be used. Furthermore, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases

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would benefit from this activity. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. In *re Fisher*, 427 F. 2d, 833, 166 USPQ 18 (CCPA 1970), indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Hence, in the absence of a showing of treating an infection caused by herpesviridae or poxiridae in a patient by administering more than once furanose-type compound, one of skill in the art is unable to fully predict possible results from the administration of multiple compounds, due to the unpredictability of the art pertaining to treatment of infections using multiple compounds together or in a formulation.

The instant specification is not seen to provide adequate guidance, which would allow the skilled artisan to extrapolate from the disclosure and examples provided, to use the claimed method commensurate in the scope with the instant claims. Applicant provides limited guidance regarding the use of multiple compounds to treat these conditions. Applicant provides information on biological activity on page 18-25. The data and evidence provided in the instant disclosure leads the examiner to doubt the objective truth of assertions of treatment of herpesviridae or poxiridae using a multiple compound protocol:

Based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not use the entire scope of the claimed invention without undue experimentation. It is suggested that applicant limit the method of claim one to administering a single active agent.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The limitation of when X is nitrogen or sulfur, which forms a 5 membered pyrrolidine or thiophene ring, is not a furanose-type carbohydrate compound. This claim is missing essential element, ie. active agent to be used in method which is indeed a furanose-type carbohydrate compound, where X is Sulfur or NH.

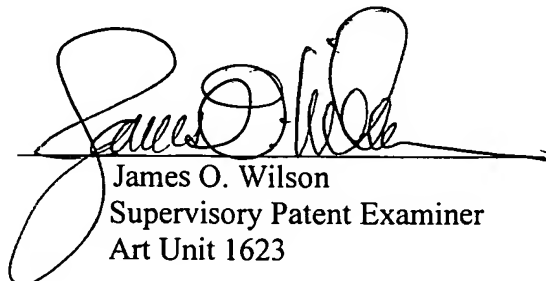
Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason H. Johnsen** whose telephone number is **571-272-3106**. The examiner can normally be reached on Mon-Friday, 8:30-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Jason H. Johnsen
Patent Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Art Unit 1623